**MHRA**
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

**gov.uk/mhra**

# Decision Cover Letter

## Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan (MHRA-100377-PIP01-21-M01) and to grant a product specific waiver

MHRA-100377-PIP01-21-M02

# Scope of the Application

## Active Substance(s)

ACALABRUTINIB

## Condition(s)

Treatment of mature B cell neoplasms

## Pharmaceutical Form(s)

Capsule hard, Film-coated tablet, Age-appropriate oral liquid dosage form, Age-appropriate oral solid dosage form

## Route(s) of Administration

ORAL USE

## Name / Corporate name of the PIP applicant

AstraZeneca UK Limited

## Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, AstraZeneca UK Limited submitted to the licensing authority on 27/10/2023 17:26 BST an application for a

The procedure started on 07/02/2024 07:24 GMT

1. The licensing authority, having assessed the application in accordance with the Human Medicines Regulations 2012, decides, as set out in the appended summary report:

to accept change(s) to the agreed paediatric investigation plan and to grant a product specific waiver

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This decision is forwarded to the applicant, together with its annex and appendix.

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# Final Decision Letter

MHRA-100377-PIP01-21-M02

Of 05/03/2024 06:54 GMT

On the adopted decision for ACALABRUTINIB (MHRA-100377-PIP01-21-M02) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Agreement on modification of a paediatric investigation plan (including modification of a waiver or deferral included in that paediatric investigation plan)

This decision applies to a for ACALABRUTINIB, Capsule hard, Film-coated tablet, Age-appropriate oral liquid dosage form, Age-appropriate oral solid dosage form , ORAL USE .

This decision is addressed to AstraZeneca UK Limited, 2 Pancras Square, London, UNITED KINGDOM, N1C 4AG

## ANNEX I

### 1. Waiver

### 1.1 Condition:

Treatment of mature B cell neoplasms The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 18 years of age Pharmaceutical form(s): Capsule hard Film-coated tablet Age-appropriate oral liquid dosage form Age-appropriate oral solid dosage form Route(s) of administration: ORAL USE Reason for granting waiver: For the paediatric population from birth to less than 1 year of age: - on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s). For the paediatric population from 1 year to less than 18 years of age - on the grounds that the specific medicinal product is likely to be ineffective

### 2. Paediatric Investigation Plan:

### 2.1 Condition(s):

Studies 1 to 8 were deleted during procedure MHRA-100377-PIP01-21-M02 and replaced with a product specific waiver.

## 2.2 Indication(s) targeted by the PIP:

Not Applicable

## 2.3 Subset(s) of the paediatric population concerned by the paediatric development:

Not Applicable

## 2.4 Pharmaceutical Form(s):

Not Applicable

## 2.5 Studies:

| Study Type | Number of Studies | Study Description |
|---|---|---|
| **Quality Measures** | 0 | Not Applicable |
| **Non-Clinical Studies** | 0 | Not Applicable |
| **Clinical Studies** | 0 | Not Applicable |
| **Extrapolation, Modeling & Simulation Studies** | 0 | Not Applicable |
| **Other Studies** | 0 | Not Applicable |
| **Other Measures** | 0 | Not Applicable |

## 3. Follow-up, completion and deferral of a PIP:

| | |
|---|---|
| **Concerns on potential long term safety and efficacy issues in relation to paediatric use:** | |
| **Date of completion of the paediatric investigation plan:** | |
| **Deferral of one or more studies contained in the paediatric investigation plan:** | |